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 7 AMERISOURCEBERGEN DRUG CORPORATION

8 **UNITED STATES DISTRICT COURT**  
 9 **EASTERN DISTRICT OF CALIFORNIA**

11 ELIZABETH A. COCHRAN,

12 Plaintiff,

13 vs.

14 MERCK & COMPANY, INC., a  
 Corporation; MCKESSON  
 15 CORPORATION; a Corporation;  
 AMERISOURCEBERGEN DRUG  
 16 CORPORATION, a Corporation; PFIZER  
 INC.; PHARMACIA CORPORATION;  
 17 G. D. SEARLE LLC, (FKA G.D.  
 SEARLE & CO.); DOES 1 to 100;  
 18 PHARMACEUTICAL DEFENDANT  
 DOES 101 to 200; DISTRIBUTOR  
 19 DEFENDANT DOES 201 to 300,  
 inclusive,

21 Defendants.

Case No. 2:06-CV-02817-GEB-DAD

**ANSWER AND AFFIRMATIVE  
 DEFENSES OF DEFENDANT  
 AMERISOURCEBERGEN DRUG  
 CORPORATION TO PLAINTIFF'S  
 COMPLAINT; DEMAND FOR JURY  
 TRIAL**

22 Defendant AMERISOURCEBERGEN DRUG CORPORATION ("Defendant" or  
 23 "AMERISOURCEBERGEN") files the following Answer to the unverified Complaint  
 24 ("Complaint") filed in the matter of ELIZABETH A. COCHRAN v. MERCK &  
 COMPANY, INC., et al. (The term "Plaintiff" as used herein shall refer to ELIZABETH  
 26 A. COCHRAN.) Defendant responds to Plaintiff's Complaint as follows:

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## **INTRODUCTION**

2 AMERISOURCEBERGEN is a wholesale distributor of pharmaceuticals, over-  
3 the-counter and health and beauty products to chain, independent pharmacy customers  
4 and hospitals. As a wholesale distributor, AMERISOURCEBERGEN distributes products  
5 manufactured by others. As to VIOXX®, AMERISOURCEBERGEN does not  
6 manufacture, produce, process, test, encapsulate, label, package or repackaging these  
7 products, nor does it make any representations or warranties as to the products' safety or  
8 efficacy. AMERISOURCEBERGEN lacks information or knowledge sufficient to admit  
9 or deny the remaining allegations contained in the introduction paragraph of the  
10 Complaint and therefore denies such allegations.

## **GENERAL ALLEGATIONS**

12       1. AMERISOURCEBERGEN is a wholesale distributor of pharmaceuticals,  
13 over-the-counter and health and beauty products to chain, independent pharmacy  
14 customers and hospitals. As a wholesale distributor, AMERISOURCEBERGEN  
15 distributes products manufactured by others. As to VIOXX®,  
16 AMERISOURCEBERGEN does not manufacture, produce, process, test, encapsulate,  
17 label, package or repackage these products, nor does it make any representations or  
18 warranties as to the products' safety or efficacy. AMERISOURCEBERGEN lacks  
19 information or knowledge sufficient to admit or deny the remaining allegations contained  
20 in Paragraph 1 of the Complaint, and its subparts and subparagraphs, and therefore denies  
21 such allegations.

22 2. AMERISOURCEBERGEN is without knowledge or information sufficient  
23 to form a belief as to the truth or falsity of the allegations of Paragraph 2 of the  
24 Complaint, and therefore denies such allegations.

25       3. AMERISOURCEBERGEN is a wholesale distributor of pharmaceuticals,  
26 over-the-counter and health and beauty products to chain, independent pharmacy  
27 customers and hospitals. As a wholesale distributor, AMERISOURCEBERGEN  
28 distributes products manufactured by others. As to VIOXX®,

1 AMERISOURCEBERGEN does not manufacture, produce, process, test, encapsulate,  
 2 label, package or repackage these products, nor does it make any representations or  
 3 warranties as to the products' safety or efficacy. AMERISOURCEBERGEN lacks  
 4 information or knowledge sufficient to admit or deny the remaining allegations contained  
 5 in Paragraph 3 of the Complaint and therefore denies such allegations.

6 4. AMERISOURCEBERGEN is without knowledge or information sufficient  
 7 to form a belief as to the truth or falsity of the allegations of Paragraph 4 of the  
 8 Complaint and its subparts and subparagraphs, and therefore denies such allegations.

9 5. AMERISOURCEBERGEN is without knowledge or information sufficient  
 10 to form a belief as to the truth or falsity of the allegations of Paragraph 5 of the  
 11 Complaint, and therefore denies such allegations.

12 6. AMERISOURCEBERGEN is a wholesale distributor of pharmaceuticals,  
 13 over-the-counter and health and beauty products to chain, independent pharmacy  
 14 customers and hospitals. As a wholesale distributor, AMERISOURCEBERGEN  
 15 distributes products manufactured by others. As to VIOXX®,  
 16 AMERISOURCEBERGEN does not manufacture, produce, process, test, encapsulate,  
 17 label, package or repackage these products, nor does it make any representations or  
 18 warranties as to the products' safety or efficacy. AMERISOURCEBERGEN lacks  
 19 information or knowledge sufficient to admit or deny the remaining allegations contained  
 20 in Paragraph 6 of the Complaint and its subparts and subparagraphs and therefore denies  
 21 such allegations.

22 7. AMERISOURCEBERGEN is a wholesale distributor of pharmaceuticals,  
 23 over-the-counter and health and beauty products to chain, independent pharmacy  
 24 customers and hospitals. As a wholesale distributor, AMERISOURCEBERGEN  
 25 distributes products manufactured by others. As to VIOXX®,  
 26 AMERISOURCEBERGEN does not manufacture, produce, process, test, encapsulate,  
 27 label, package or repackage these products, nor does it make any representations or  
 28 warranties as to the products' safety or efficacy. AMERISOURCEBERGEN lacks

1 information or knowledge sufficient to admit or deny the remaining allegations contained  
 2 in Paragraph 7 of the Complaint and its subparts and subparagraphs, and therefore denies  
 3 such allegations.

4 **AFFIRMATIVE DEFENSES**

5 **FIRST AFFIRMATIVE DEFENSE**

6 8. The Complaint and all causes of action asserted against Defendant fail to  
 7 state facts sufficient to constitute a cause of action.

8 **SECOND AFFIRMATIVE DEFENSE**

9 9. Federal law preempts Plaintiff's claims. Plaintiff has asserted claims for  
 10 relief which, if granted, would constitute an impermissible burden by this Court on  
 11 Federal laws, regulations, and policies relating to the development and marketing of  
 12 products, in violation of the Supremacy Clause, Article VI of the Constitution of the  
 13 United States.

14 **THIRD AFFIRMATIVE DEFENSE**

15 10. The causes of action alleged in the Complaint are barred by the applicable  
 16 statutes of limitations and/or statutes of repose, including but not limited to California  
 17 *Code of Civil Procedure* §§ 335.1 and 338 and former § 340(3), California *Business and*  
 18 *Professions Code* § 17208, and *California Civil Code* § 1783.

19 **FOURTH AFFIRMATIVE DEFENSE**

20 11. During the time periods alleged in the Complaint, Plaintiff failed to exercise  
 21 ordinary care on Plaintiff's own behalf for Plaintiff's safety. Plaintiff's recklessness,  
 22 carelessness and/or negligence caused any injury and damage that Plaintiff may have  
 23 sustained. Plaintiff's right to recover should be diminished by Plaintiff's proportional  
 24 share of fault.

25 **FIFTH AFFIRMATIVE DEFENSE**

26 12. Plaintiff failed to mitigate any damage that Plaintiff may have sustained.  
 27 Plaintiff failed to exercise reasonable care to avoid the consequences of harm, if any.  
 28 Among other things, Plaintiff failed to use reasonable diligence in caring for any injury,

1 use reasonable means to prevent aggravation of any injury, and/or take reasonable  
 2 precautions to reduce any injury and damage.

3 **SIXTH AFFIRMATIVE DEFENSE**

4 13. During the time periods alleged in the Complaint, Plaintiff had full  
 5 knowledge of the risks and possible adverse effects pertaining to the use of the products.  
 6 Defendant alleges that part or all of the injuries, damages, or losses, if any, that Plaintiff  
 7 claim to have sustained arose from or were caused by such risks. Plaintiff was aware of,  
 8 accepted, and assumed the risks and possible adverse effects. Plaintiff's recovery, if any,  
 9 should be diminished, reduced, offset, or barred by Plaintiff's assumption of the risks and  
 10 informed consent.

11 **SEVENTH AFFIRMATIVE DEFENSE**

12 14. Defendant denies that Plaintiff suffered injuries or incurred any damages, or  
 13 that any defendant is liable. If Plaintiff did suffer any injuries or incur any damages, any  
 14 injuries or damages were caused, in whole or in part, by the acts or omissions of persons  
 15 or entities other than Defendant or superseding or intervening causes over which  
 16 Defendant had no control. If there is any negligence or liability by any defendant, it is the  
 17 sole and exclusive negligence and liability of others and not this answering Defendant.

18 **EIGHTH AFFIRMATIVE DEFENSE**

19 15. The intervening or superseding cause of any injury allegedly sustained by  
 20 the Plaintiff may be conduct which is illicit, criminal, or otherwise improper, and for  
 21 which conduct Defendant cannot be held responsible.

22 **NINTH AFFIRMATIVE DEFENSE**

23 16. Plaintiff's alleged damages, injuries, or losses, if any, were not proximately  
 24 caused by any alleged act, omission, or breach of duty by Defendant but were caused in  
 25 whole or in part by the acts or omissions of Plaintiff and/or others so that the principles of  
 26 contributory negligence, comparative fault and/or assumption of the risk apply.

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**TENTH AFFIRMATIVE DEFENSE**

17. Plaintiff's claims are barred in whole or in part because they have been  
 3 improperly joined in this action.

**ELEVENTH AFFIRMATIVE DEFENSE**

18. If any of the other parties are negligent, legally responsible, or otherwise at  
 6 fault for the damages alleged in the Master Complaint, and if there is a finding of any  
 7 liability in favor of Plaintiff or settlement or judgment against Defendant, Defendant  
 8 requests that the Court or Jury make an apportionment of fault among all parties as  
 9 permitted by *Li v. Yellow Cab Co.* and *American Motorcycle Association v. Superior*  
 10 *Court*. Defendant further requests a judgment and declaration of partial indemnification  
 11 and contribution against all other parties or persons in accordance with the apportionment  
 12 of fault.

**TWELFTH AFFIRMATIVE DEFENSE**

19. Plaintiff's claims are barred in whole or in part because they have been filed  
 15 in an improper venue.

**THIRTEENTH AFFIRMATIVE DEFENSE**

20. Plaintiff's alleged injuries were the direct and proximate result of an  
 18 idiosyncratic reaction which was not reasonably foreseeable, or was not the result of any  
 19 conduct or negligence on the part of Defendant; and/or was not the result of any defect in  
 20 any product distributed or sold by Defendant.

**FOURTEENTH AFFIRMATIVE DEFENSE**

21. The hazards of foreseeable uses and misuses of the product are open and  
 23 obvious.

**FIFTEENTH AFFIRMATIVE DEFENSE**

22. After the products left the possession and control of Defendant, if in fact any  
 25 products were ever in the possession or control of Defendant, the products were  
 26 redesigned, modified, altered, or subjected to treatment that substantially changed their  
 27 character without Defendant's knowledge. Any alleged defect resulted, if at all, from the  
 28

1 redesign, modification, alteration, treatment or other change of the products after  
 2 Defendant relinquished possession of and control over any of the products.

3 **SIXTEENTH AFFIRMATIVE DEFENSE**

4 23. The design, manufacture, and marketing of the products were in conformity  
 5 with the "state of the art" existing at the time of such design, manufacture, and marketing.

6 **SEVENTEENTH AFFIRMATIVE DEFENSE**

7 24. The learned intermediary doctrine bars Plaintiff's recovery of any damages.  
 8 Any duty to warn Plaintiff of the risks and hazards associated with the products was  
 9 discharged by providing adequate warning to physicians.

10 **EIGHTEENTH AFFIRMATIVE DEFENSE**

11 25. To the extent that Plaintiff alleges a failure to warn by Defendant, Defendant  
 12 alleges that the manufacturers, physician, and other health care providers associated with  
 13 the products knew, or should have been aware, of any risk and hazard that Plaintiff and/or  
 14 Plaintiff's decedent alleges rendered the products defective and that allegedly caused  
 15 Plaintiff's and/or Plaintiff's decedent's injuries and damages, if any. To the extent that  
 16 such manufacturers, physician, and other health care providers failed to advise, inform, or  
 17 warn Plaintiff of such risks and hazards, such failure is imputed to Plaintiff under agency  
 18 principles and Plaintiff and/or Plaintiff's decedent knowingly and voluntarily assumed  
 19 the risk of any injury as a result of the consumption of, administration of, or exposure to  
 20 the product.

21 **NINETEENTH AFFIRMATIVE DEFENSE**

22 26. The Complaint is barred due to the lack of privity, or a "transaction,"  
 23 between Plaintiff and Defendant.

24 **TWENTIETH AFFIRMATIVE DEFENSE**

25 27. This Court lacks personal jurisdiction over this answering Defendant.

26 **TWENTY-FIRST AFFIRMATIVE DEFENSE**

27 28. Plaintiff's claims are barred in whole or in part by the doctrines of accord  
 28 and satisfaction, good faith, consent, res judicata, payment and release, waiver, collateral

1 estoppel, judicial estoppel, equitable estoppel, unclean hands, laches, and/or statutory and  
 2 regulatory compliance.

3 **TWENTY-SECOND AFFIRMATIVE DEFENSE**

4 29. The products were not used in the manner in which they were intended to be  
 5 used. The products were used in a manner that was abnormal and not reasonably  
 6 foreseeable by Defendant. Such misuse of the products proximately caused or  
 7 contributed to Plaintiff's alleged damages, injuries, and losses, if any.

8 **TWENTY-THIRD AFFIRMATIVE DEFENSE**

9 30. The imposition of punitive or exemplary damages against Defendant or that  
 10 are in any way imputed against the interests of Defendant would violate the ruling in  
 11 *State Farm Mut. Automobile Ins. Co. v. Campbell* (2003) 538 U.S. 408, and Defendant's  
 12 constitutional rights under: the Due Process clauses in the Fifth and Fourteenth  
 13 Amendments to the Constitution of the United States; the Sixth Amendment to the  
 14 Constitution of the United States; the Double Jeopardy clause in the Fifth Amendment to  
 15 the Constitution of the United States; comparable provisions contained within the  
 16 California Constitution; the common law and public policies of California; and applicable  
 17 statutes and court rules, including but not limited to, imposition of punitive damages and  
 18 determination of such an award:

19 (a) by a jury when the jury is: (i) not given standards of sufficient clarity for  
 20 determining the appropriateness, and the appropriate size, of a punitive  
 21 damages award; (ii) not adequately and clearly instructed on the limits on  
 22 punitive damages imposed by the principles of deterrence and punishment;  
 23 (iii) not expressly prohibited from awarding punitive damages, or  
 24 determining the amount of such an award, in whole or in part, on the basis of  
 25 invidiously discriminatory characteristics, including the corporate status,  
 26 wealth, or state of residence of Defendant; (iv) permitted to award punitive  
 27 damages under a standard for determining liability for such damages which  
 28 is vague and arbitrary and does not define with sufficient clarity the conduct

1                   or mental state which makes punitive damages permissible; and (v) not  
 2                   subject to trial court and appellate judicial review for reasonableness, the  
 3                   furtherance of legitimate purpose, and the basis of objective standards;  
 4                   (b) where applicable law is impermissibly vague, imprecise, or inconsistent;  
 5                   (c) subject to no predetermined limit, such as a maximum multiple of  
 6                   compensatory damages or a maximum amount; and  
 7                   (d) based upon anything other than Defendant's conduct in connection with the  
 8                   sale of the products alleged in this litigation, or in any other way subjecting  
 9                   Defendant to impermissible multiple punishment for the same alleged  
 10                  wrong.

#### **TWENTY-FOURTH AFFIRMATIVE DEFENSE**

12                  31. While continuing to deny any and all liability, Defendant states that if the  
 13                  court determines that Plaintiff is entitled to assert a claim for punitive damages, such  
 14                  claim cannot be permitted to go forward until the trier of fact determines that punitive  
 15                  damages should be considered, and, ultimately all issues regarding punitive damages  
 16                  should be bifurcated at trial. Any award for punitive or exemplary damage absent  
 17                  bifurcating trial as to issues of compensatory and exemplary damages would be in  
 18                  violation of Defendant's rights to due process under the United States Constitution and  
 19                  the correlative provisions of California law.

#### **TWENTY-FIFTH AFFIRMATIVE DEFENSE**

21                  32. At all times, any products distributed by Defendant were distributed in  
 22                  compliance with all applicable federal, state and local laws and regulations, and rules  
 23                  promulgated and enforced by the Food and Drug Administration. The products were  
 24                  subject to and received pre-market approval by the Food and Drug Administration under  
 25                  52 Stat. 1040, 21 U.S.C. § 301. Compliance with such laws, regulations, and rules  
 26                  demonstrates that due care and reasonable prudence were exercised in the design,  
 27                  manufacture, and promotion of the subject pharmaceutical product and that said product  
 28                  was not defective in any way.

## **TWENTY-SIXTH AFFIRMATIVE DEFENSE**

33. Any damages, injuries and/or losses alleged to have been suffered by Plaintiff has been mitigated, in whole or in part, by reimbursement from collateral sources and therefore, Plaintiff's claims against Defendant are barred and/or reduced by any applicable set off.

## **TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

34. At all times, Defendant's acts or omissions were privileged, justified, fair and undertaken in the good faith exercise of a valid business purpose.

## **TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

35. Plaintiff cannot demonstrate the necessary elements to support the request for injunctive relief, including without limitation, a threat of imminent or immediate harm.

## **TWENTY-NINTH AFFIRMATIVE DEFENSE**

36. Any alleged act or omission by Defendant concerning the manufacture, warning, labeling, advertising and sale of VIOXX® referred to in the Complaint, was at all times, the duty of an entity other than Defendant. Defendant acted in good faith concerning all services for which it had a duty to provide as referred to in the Complaint.

## THIRTIETH AFFIRMATIVE DEFENSE

37. Plaintiff's claims for disgorgement or restitution are barred under the decision in *Kraus v. Trinity Management Services, Inc.* (2000) 23 Cal.4th 116 and related authority.

## THIRTY-FIRST AFFIRMATIVE DEFENSE

38. Plaintiff's alleged injuries or illnesses preexisted or were suffered after the alleged use of the products, and Plaintiff's alleged injuries or illnesses were neither caused nor exacerbated by said alleged use.

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## THIRTY-SECOND AFFIRMATIVE DEFENSE

39. Plaintiff's injuries were caused or contributed to by their failure to follow the directions and precautions provided by the product's manufacturer(s).

## THIRTY-THIRD AFFIRMATIVE DEFENSE

40. Plaintiff's breach of warranty claims are barred because Plaintiff failed to give adequate and timely notice of his alleged claims against Defendant and/or because the alleged warranties were disclaimed.

## THIRTY-FOURTH AFFIRMATIVE DEFENSE

41. Defendant's alleged business practices with respect to the subject product were lawful, fair, truthful, not misleading or deceptive, not fraudulent, and were justified based on the state of medical and scientific knowledge available during the relevant time and were in compliance with the applicable laws, regulations, and rules within the meaning of either *Business and Professions Code* Section 17200, et seq. or *Business and Professions Code* Section 17500, et seq.

## THIRTY- FIFTH AFFIRMATIVE DEFENSE

42. Plaintiff's claimed injuries and/or damages are so remote, speculative or contingent that Plaintiff's claims must be barred on public policy grounds.

## THIRTY-SIXTH AFFIRMATIVE DEFENSE

43. The conduct alleged in the Complaint does not plead a “violation of law” sufficient to provide the necessary predicate for an “unlawful” business practices claim, or any other claim, under either *Business and Professions Code* Section 17200, et seq. or *Business and Professions Code* Section 17500 et seq.

## THIRTY-SEVENTH AFFIRMATIVE DEFENSE

44. Plaintiff's claims under *Business and Professions Code* Section 17200, et seq. or *Business and Professions Code* Section 17500 et seq. are barred in whole or in part under principles of substantive and procedural due process.

## THIRTY-EIGHTH AFFIRMATIVE DEFENSE

45. Plaintiff's claims under *Business and Professions Code* Section 17200, et

1 seq. or *Business and Professions Code* Section 17500, et seq. are barred in whole or in  
 2 part because Plaintiff do not qualify as private attorneys general, and for that reason,  
 3 among others, lack standing to prosecute a claim for injunctive or monetary relief.

4 **THIRTY-NINTH AFFIRMATIVE DEFENSE**

5 Plaintiff's claims under *Business and Professions Code* Section 17200, et  
 6 seq. or *Business and Professions Code* Section 17500, et seq. are barred in whole or in  
 7 part because there is no basis for injunctive relief in this action and Plaintiff has an  
 8 adequate remedy at law.

9 **FORTIETH AFFIRMATIVE DEFENSE**

10 Plaintiff's claims under *Business and Professions Code* Section 17200, et  
 11 seq. or *Business and Professions Code* Section 17500, et seq. are barred in whole or in  
 12 part by the doctrine of primary jurisdiction. The subject of pharmaceutical product and  
 13 any advertising regarding such product are regulated by the Food and Drug  
 14 Administration and as such, answering Defendant requests that this Court, sitting in  
 15 equity, abstain from hearing claims under Sections 17200, et seq. and 17500, et seq.,  
 16 which are accordingly preempted by Federal law.

17 **FORTY-FIRST AFFIRMATIVE DEFENSE**

18 The Plaintiff is barred from recovery against Defendant because of the  
 19 sophisticated user doctrine.

20 **FORTY-SECOND AFFIRMATIVE DEFENSE**

21 Plaintiff's strict liability claims are barred under the principles set forth in  
 22 *Brown v. Superior Court* (1988) 44 Cal.3d 1088.

23 **FORTY-THIRD AFFIRMATIVE DEFENSE**

24 Plaintiff's claim, if any, for loss of consortium is barred because it is  
 25 derivative of the injured Plaintiff's/decedent's claim, which fails pursuant to the  
 26 affirmative defenses set forth herein.

27 **FORTY-FOURTH AFFIRMATIVE DEFENSE**

28 Defendant is a provider of services, not products, and thus is not strictly

1 liable under California law.

2 **FORTY-FIFTH AFFIRMATIVE DEFENSE**

3 52. Plaintiff's Complaint fails to allege ultimate facts sufficient to state a cause  
4 of action predicated upon negligence, strict liability, breach of implied warranty, breach  
5 of express warranty, failure to warn or deceit by concealment.

6 **FORTY-SIXTH AFFIRMATIVE DEFENSE**

7 53. Plaintiff's claims of any non-economic damages are subject to *California*  
8 *Civil Code* §1431.2, which is applicable to the Complaint and each cause of action  
9 therein.

10 **FORTY-SEVENTH AFFIRMATIVE DEFENSE**

11 54. The product at issue in this litigation is not defective or unreasonably  
12 dangerous because it is a prescription pharmaceutical bearing adequate warnings, and is  
13 subject to the comment j exception to strict liability as set forth in § 402A of the  
14 Restatement (Second) of Torts (1965), and/or because it is a prescription pharmaceutical  
15 that is unavoidably unsafe pursuant to comment k of § 402A of the Restatement (Second)  
16 of Torts (1965).

17 **FORTY-EIGHT AFFIRMATIVE DEFENSE**

18 55. Plaintiff's claims are barred in whole or in part because the subject  
19 pharmaceutical product "provides net benefits for a class of patients" within the meaning  
20 of Comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

21 **FORTY-NINTH AFFIRMATIVE DEFENSE**

22 56. Plaintiff's claims are barred under Section 4, et seq., of the Restatement  
23 (Third) of Torts: Products Liability.

24 **FIFTIETH AFFIRMATIVE DEFENSE**

25 57. Plaintiff's claims, if any, related to negligence per se are barred, in whole or  
26 in part, because there is no statute violated by this Defendant.

27 **FIFTY-FIRST AFFIRMATIVE DEFENSE**

28 58. Plaintiff's claims are barred in whole or in part by the deference given to the

1 primary jurisdiction of the Food and Drug Administration over the subject  
 2 pharmaceutical product under applicable federal laws, regulations, and rules. These  
 3 claims are thus preempted by Federal law.

4 **FIFTY-SECOND AFFIRMATIVE DEFENSE**

5 59. Plaintiff's claims are barred in whole or in part because there is no private  
 6 right of action concerning matters regulated by the Food and Drug Administration under  
 7 applicable federal laws, regulations, and rules.

8 **FIFTY-THIRD AFFIRMATIVE DEFENSE**

9 60. Plaintiff's claims are barred in whole or in part because Plaintiff lack  
 10 standing to bring such claims.

11 **FIFTY-FOURTH AFFIRMATIVE DEFENSE**

12 61. Plaintiff's claims are barred in whole or in part because they fail to meet the  
 13 requirements of *California Code of Civil Procedure* §§ 377.30, et seq., and 377.60, et  
 14 seq., governing a decedent's cause of action and wrongful death actions.

15 **FIFTY-FIFTH AFFIRMATIVE DEFENSE**

16 62. Plaintiff's claims are barred to the extent they are made by, or on behalf of,  
 17 out of state Plaintiff or Plaintiff's decedent, or arose from events occurring out of state,  
 18 are barred in whole or in part under principles of forum non conveniens and due process.

19 **FIFTY-SIXTH AFFIRMATIVE DEFENSE**

20 63. Plaintiff's claims are barred in whole or in part because the Complaint fails  
 21 to join necessary and indispensable parties.

22 **FIFTY-SEVENTH AFFIRMATIVE DEFENSE**

23 64. Plaintiff's Consumer Legal Remedies Act cause of action is barred because  
 24 it fails to meet the requirements of *California Civil Code* §§ 1750, et seq.

25 **FIFTY-EIGHTH AFFIRMATIVE DEFENSE**

26 65. Defendant did not design, manufacture, formulate, distribute, market, sell,  
 27 research, develop, test or supply the VIOXX® that was alleged to have been ingested by  
 28 Plaintiff and/or any of the ingredients contained therein.

## **FIFTY-NINTH AFFIRMATIVE DEFENSE**

66. Plaintiff failed to allege specific facts that Defendant distributed and/or supplied the subject product that Plaintiff allegedly ingested. Accordingly, Plaintiff failed to plead facts sufficient to show an actual connection between Defendant's alleged conduct and the Plaintiff's purported injury and Defendant has, therefore, been fraudulently joined.

## SIXTIETH AFFIRMATIVE DEFENSE

67. Plaintiff's vague allegations are legal conclusions directed at "defendants" in general and fail to support any claims specific to Defendant.

## SIXTY-FIRST AFFIRMATIVE DEFENSE

68. Plaintiff's claims are barred by the applicable prescriptive periods or statutes of limitations provided for such claims.

## SIXTY-SECOND AFFIRMATIVE DEFENSE

69. Defendant denies that the products distributed by it caused or contributed to the alleged injuries of Plaintiff and further denies that it is liable to Plaintiff for the claims alleged or for any other claims whatsoever.

## SIXTY-THIRD AFFIRMATIVE DEFENSE

70. Defendant did not make any material representation of fact regarding the products it distributes which was not true, or if such representation was made, which Defendant specifically denies, then AMERISOURCEBERGEN did not make such representation with the intent to either deceive or to induce Plaintiff to act in justifiable reliance.

## SIXTY-FOURTH AFFIRMATIVE DEFENSE

71. Plaintiff did not justifiably rely, in any fashion whatsoever, upon any statement, representation, advice or conduct of AMERISOURCEBERGEN, and did not act upon any statement, representation advice or conduct to their detriment.

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## SIXTY-FIFTH AFFIRMATIVE DEFENSE

72. Defendant asserts that as of the relevant times alleged in the Complaint, it did not know and, in light of the then existing reasonable available scientific and technological knowledge, could not have known of: (1) the design characteristics, if any, that allegedly caused the injuries and damages complained of in the Petition; (2) the alleged danger of any such design characteristics.

## SIXTY-SIXTH AFFIRMATIVE DEFENSE

73. Plaintiff's claims are barred, in whole or in part, to the extent Plaintiff, or any state entity acting on behalf of Plaintiff, has released, settled, entered into an accord and satisfaction or otherwise compromised Plaintiff's claims.

## SIXTY-SEVENTH AFFIRMATIVE DEFENSE

74. Defendant is entitled to set-off, should any damages be awarded against it, in the amount of damages or settlement amounts recovered by Plaintiff, or any state entity acting on behalf of Plaintiff, with respect to the same alleged injuries. Defendant is also entitled to have any damages that may be awarded to Plaintiff reduced by the value of any benefit or payment to Plaintiff, or any state entity acting on behalf of Plaintiff, from any collateral source.

## SIXTY-EIGHTH AFFIRMATIVE DEFENSE

75. Defendant asserts that it has complied with all applicable state and federal laws relating to the distribution and/or sale of pharmaceuticals.

## SIXTY-NINTH AFFIRMATIVE DEFENSE

76. To the extent Plaintiff assert claims based upon an alleged failure by Defendant to warn Plaintiff directly of alleged dangers associated with the use of VIOXX®, such claims are barred under the learned intermediary doctrine.

## SEVENTIETH AFFIRMATIVE DEFENSE

77. Defendant reserves the right to rely upon other affirmative defenses as they become reasonably available and apparent during the discovery proceedings in this case. Defendant reserves the right to amend this Answer to assert any such defenses.

**WHEREFORE**, AMERISOURCEBERGEN prays for relief as follows:

1. That Plaintiff take nothing by this action;
2. That judgment be entered in favor of AMERISOURCEBERGEN and against Plaintiff;
3. That AMERISOURCEBERGEN be awarded costs of suit herein; and
4. For such other and further relief as the Court may deem just and proper.

Dated: December 29, 2006 Respectfully Submitted,

## MORRIS POLICH & PURDY LLP

By: /s/ Kanika D. Corley, Esq.

Anthony G. Brazil

Kanika D. Corley

Attorneys for Defendant  
**AMERISOURCEBERGEN DRUG  
CORPORATION**

**DEMAND FOR JURY TRIAL**

Defendant hereby demands trial by jury in this matter.

Dated: December 29, 2006

## MORRIS POLICH & PURDY LLP

By: /s/ Kanika D. Corley

Anthony G. Brazil

Kanika D. Corley

Atorneys for Defendant

# AMERISOURCEBERGEN DRUG CORPORATION

**ELECTRONIC PROOF OF SERVICE**

I am employed in the County of Los Angeles, State of California. I am over the age of eighteen (18) years and am not a party to the within action.

On December 29, 2006, pursuant to the Court's Electronic Filing System, I

submitted an electronic version of the following document via file transfer protocol to ECF (Electronic Case Filing)

submitted a hard copy of the following document to ECF (Electronic Case Filing) by

facsimile  overnight delivery

**“ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANT  
AMERISOURCEBERGEN DRUG CORPORATION TO PLAINTIFF’S COMPLAINT;  
DEMAND FOR JURY TRIAL”**

**STATE** I declare under penalty of perjury under the laws of the state of California, that the above is true and correct.

**FEDERAL** I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made

Executed on December 29, 2006, at Los Angeles, California.

Elena Juarez-Holguin  
Elena Juarez-Holguin